

AHRQ Comparative Effectiveness Review

Surveillance Program

CER # 45:

Self-Measured Blood Pressure Monitoring:
Comparative Effectiveness

Original release date:

January 31, 2012

Surveillance Report:

November 14, 2012

Key Findings:

- KQ1, KQ2, KQ3, KQ4, and KQ5 are up to date
- Expert opinion: KQ's 1-5 are still valid. One expert stated that one of the conclusions for KQ 1 and one of the conclusions for KQ 2 are invalid.
- There are no new significant safety concerns

Summary Decision:

This CER's priority for updating is **Low**

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Acknowledgments

The authors gratefully acknowledge the following content experts for their contributions to this project: Drs Hayden Bosworth, Steven Brown, Vincent Canzanello, Beverly Green, Raymond Townsend, and Anthony Viera.

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1. Introduction

The purpose of this mini-report is to apply the methodologies developed by the Ottawa and RAND Evidence-based Practice Centers, and to determine whether the Comparative Effectiveness Review (CER) No. 45 (Comparative Effectiveness of Self-Measured Blood Pressure Monitoring)¹, is in need of updating. This CER was originally released in January 31, 2012 and thus due for a surveillance assessment in August 2012.

This CER included 49 unique studies identified by using searches through July 2011 and addressed five key questions to evaluate the effectiveness of self-measured blood pressure monitoring (SMBP) on outcomes in adults and children with hypertension. The use of SMBP with and without additional support versus usual treatment was reviewed.

The key questions of the original CER are as follows:

Key Question #1: In people with hypertension (adults and children), does self-measured blood pressure monitoring (SMBP), compared with usual care or other interventions without SMBP, have an affect on clinically important outcomes?

- a. How does SMBP monitoring compare with usual care or other interventions without SMBP in its effect on relevant clinical outcomes (cardiovascular events, mortality, patient satisfaction, quality of life, and adverse events related to antihypertensive agents?)
- b. How does SMBP monitoring compare with usual care or other interventions without SMBP in its effect on relevant surrogate outcomes (cardiac measures: LVH, LVM, LVMI) and intermediate outcomes (Blood pressure (BP) control, BP treatment adherence, or health care process measures)?

Key question # 2: In trials of SMBP monitoring, how do clinical, surrogate, and intermediate outcomes (including SMBP monitoring adherence) vary by the type of additional support provided?

Key question # 3: How do different devices for SMBP monitoring compare with each other (specifically semiautomatic or automatic vs. manual) in their effects on clinical, surrogate, and intermediate outcomes (including SMBP monitoring adherence)?

Key question # 4: In trials of SMBP monitoring, how does achieving BP control relate to clinical and surrogate outcomes?

Key question # 5: How does adherence with SMBP monitoring vary by patient factors?

The conclusion(s) for each key question are found in the executive summary of the CER report.¹

2. Methods

We followed *a priori* formulated protocol to search and screen literature, extract relevant data, and assess signals for updating. The identification of an updating signal (qualitative or quantitative) would be an indication that the CER might need to be updated. The Food and Drug Administration (FDA), Health Canada, and Medicines and Healthcare products Regulatory Agency (MHRA) surveillance alerts received from the Emergency Care Research Institute (ECRI) were examined for any relevant material for the present CER. Clinical expert opinion was also sought. All of this evidence was taken into consideration leading to a consensus-based decision on whether any given conclusion warrants updating (up to date, possibly out of date, or out of date). Based on this assessment, the CER was categorized into one of the three updating priority groups: high priority, medium priority, or low priority. Further details on the Ottawa EPC and RAND methods used for this project are found elsewhere.²⁻⁴

2.1 Literature Searches

The CER search strategies were reconstructed in Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) <1946 to August 13 2012> and EBM Reviews (OVID)- Cochrane Central Register of Controlled Trials <July 2012>.

The syntax and vocabulary included both controlled MeSH subject headings and keywords. The search was limited to five general medical journals (Annals of Internal Medicine, BMJ, JAMA, Lancet, and New England Journal of Medicine) and five specialty journals (American Journal of Hypertension, Hypertension, Journal of Human Hypertension, Journal of Hypertension, Circulation). Further details on the search strategies are provided in the Appendix A of this mini-report.

2.2 Study Selection

All identified bibliographic records were screened using the same inclusion/exclusion criteria as described in the original CER.¹

2.3 Expert Opinion

In total, 13 experts (peer reviewers and/or members of the technical expert panel of the original report) were requested to provide their feedback (in a pre-specified matrix table) on whether the conclusions as outlined in the Executive Summary of the original CER were still valid.

2.4 Check for Qualitative and Quantitative Signals

All relevant reports eligible for inclusion in the CER were examined for the presence of qualitative and quantitative signals using the Ottawa EPC method (see more details in Appendix B). CERs with no meta-analysis were examined for qualitative signals only. For any CER that

contains meta-analysis(es), we first assess for the qualitative signal(s), and if no qualitative signal(s) are found, we then assess for quantitative signal(s). The identification of an updating signal (qualitative or quantitative) would be an indication that the CER might be in need of updating. The definition and categories of updating signals are presented in Appendix B and publications.^{2,3}

2.5 Compilation of Findings and Conclusions

All the information obtained during the updating process (i.e., data on qualitative/quantitative signals, the expert opinions, and safety surveillance alerts) was collated, summarized and presented into a table. We determined whether the conclusions of the CER warranted updating using a four category scheme:

- Original conclusion is still **up to date** and this portion of CER does not need updating
- Original conclusion is **possibly out of date** and this portion of CER may need updating
- Original conclusion is **probably out of date** and this portion of CER may need updating
- Original conclusion is **out of date** and this portion of CER is in need of updating

We used the following factors when making our assessments to categorize the CER conclusions:

- If we found no new evidence or only confirmatory evidence and all responding experts assessed the CER conclusion as still valid, we classified the CER conclusion as still up to date.
- If we found some new evidence that might change the CER conclusion, and /or a minority of responding experts assessed the CER conclusion as having new evidence that might change the conclusion, then we classified the CER conclusion as possibly out of date.
- If we found substantial new evidence that might change the CER conclusion, and/or a majority of responding experts assessed the CER conclusion as having new evidence that might change the conclusion, then we classified the CER conclusion as probably out of date.
- If we found new evidence that rendered the CER conclusion out of date or no longer applicable, we classified the CER conclusion as out of date. Recognizing that our literature searches were limited, we reserved this category only for situations where a limited search would produce prima facie evidence that a conclusion was out of date, such as the withdrawal of a drug or surgical device from the market, a black box warning from FDA, etc.

2.6 Determining Priority for Updating

Determining the priority groups (i.e., Low, Medium, and High) for updating any given CER is based on the following two criteria:

- How many conclusions of the CER are up to date, possibly out of date, or certainly out of date?
- How out of date are conclusions? (e.g., consideration of magnitude/direction of changes in estimates, potential changes in practice or therapy preference, safety issue including withdrawn from the market drugs/black box warning, availability of a new treatment)

3. Results

3.1 Update Literature Searches and Study Selection

A total of 121 bibliographic records were identified from MEDLINE of which 34 records were deemed eligible for full text screening. None of the screened full text records were included in this assessment report. Some of the reasons for exclusions were: not meeting general eligibility criteria; not having relevant outcomes of interest; and not using SMBP monitoring for at least 8 weeks.

One expert-nominated study was included.⁵ Please refer to sections 3.2 and 3.4 for more information on this study.

3.2 Signals for Updating in Newly Identified Studies

3.2.1 Study overview

This assessment report included only one study.⁵ Although this study does not directly answer key question 4, we included it in this assessment because the earlier publications of this study were referenced under the ongoing research section of the original CER: “Trial was expected to inform the choice of the home BP target, although it does appear that it will provide evidence as to the effect of BP monitoring, per se”.¹ As such, we documented the findings of the study that relate to the choice of the home blood pressure target.

The study, population, treatment characteristics, and results for the included study⁵ are presented in Appendix C (Evidence Table). The included study was a randomized controlled trial (RCT) that followed 3518 patients with untreated home blood pressure with a median follow up time of 5.31 years. The study randomized the participants into usual control (UC) (125-134/80-84 mm Hg) versus tight control (TC) (>125/>80 mm Hg) of home blood pressure (HBP) and to initiation of anti-hypertensive drugs using a 2X 3 design.

3.2.2 Qualitative signals

See also Table 1 (Summary Table), Appendix B, and Evidence Table (Appendix C)

Key question #1

In people with hypertension (adults and children), does self-measured blood pressure monitoring (SMBP), compared with usual care or other interventions without SMBP, have an effect on clinically important outcomes?

- a. How does SMBP monitoring compare with usual care or other interventions without SMBP in its effect on relevant clinical outcomes (cardiovascular events, mortality, patient satisfaction, quality of life, and adverse events related to antihypertensive agents)?
- b. How does SMBP monitoring compare with usual care or other interventions without SMBP in its effect on relevant surrogate outcomes (cardiac measures: LVH, LVM, LVMI) and intermediate outcomes (BP control, BP treatment adherence, or health care process measures)?

No new evidence identified to answer Key Question # 1. **No Signal**

Key question #2

In trials of SMBP monitoring, how do clinical, surrogate, and intermediate outcomes (including SMBP monitoring adherence) vary by the type of additional support provided?

No new evidence identified to answer to Key Question 2. **No Signal**

Key question # 3

How do different devices for SMBP monitoring compare with each other (specifically semiautomatic or automatic vs. manual) in their effects on clinical, surrogate, and intermediate outcomes (including SMBP monitoring adherence)?

No new evidence identified to answer Key Question 3. **No Signal**

Key question # 4

In trials of SMBP monitoring, how does achieving BP control relate to clinical and surrogate outcomes?

In summary, this trial studied two groups -TC versus UC (<125/<80 mm Hg versus 125-134/80-84 mm Hg). After a median follow up period of 5.3 years, there was no difference between TC vs. UC treatment groups in cardiovascular death plus stroke and myocardial infarction (26 versus 25 patients - hazard ratio, 1.02; 95% CI 0.59-1.77; P=0.94). The results showed that the TC group achieved the lower HBP target less frequently than the UC group (37.4% versus 63.5%; $p<0.0001$), but had a greater reduction in HBP (21.3/13.1 mm Hg versus 22.7/13.9 mm Hg, $P=0.018/0.020$). In addition the TC group had a greater mean defined daily dose of the antihypertensive drugs. (1.82 versus 1.74, $P=0.045$).

The study concluded that achieving a target systolic blood pressure of 130 mm Hg by adjusting antihypertensive drug treatments guided by home blood pressure measurements was both achievable and safe.

Although these results are interesting, because they do not directly answer key question #4, they do not change the findings of the review and therefore there is no qualitative signal for this key question. **No Signal**

Key question # 5

How does adherence with SMBP monitoring vary by patient factors?

No new evidence identified to answer Key Question 5. **No Signal**

3.2.3 Quantitative signals

See also Table 1 (Summary Table), Appendix B, and Evidence Table (Appendix C)

Key question #1

Comparison of SMBP monitoring versus usual care

No new evidence. **No Signal**

Key question #2

Comparison by type of additional support

No new evidence. **No Signal**

Key question # 3

Comparison of devices

No new evidence. **No Signal**

Key question # 4

Achieving BP control

The study did not contribute new evidence. **No Signal**

Key question # 5

Adherence with SMPB monitoring

No new evidence. **No Signal**

3.3 Safety surveillance alerts

No safety alerts were identified.

3.4 Expert opinion

Six of the 13 clinical experts provided responses to the matrix table (Appendix D). Furthermore, four additional studies were nominated to be included in this report.⁵⁻⁸

One of the study was included in this report⁵ and the other three were excluded.⁶⁻⁸ The three studies were excluded because: The results for one study were pooled and thus we could not distinguish between the two comparator groups,⁶ the study did not have an appropriate comparison group,⁷ and the third nomination was a statement guide that did not have data that answered any of the key questions in the report.⁸

With respect to KQ's 3, 4 and 5 all six experts agreed that there was no new evidence to invalidate the findings of the CER thereby rendering the conclusions of those key questions still valid.

For KQ1, there was one expert that stated that one of the conclusions was no longer valid. As explained previously, both references nominated to support this statement were excluded from the report.^{7,8}

The remaining five experts agreed that all of the conclusions for KQ1 remained valid.

Similarly for KQ2, there was one expert that stated that two of the conclusions were no longer valid and both references submitted as support for this statement were excluded from the report.^{7,8} The remaining five experts agreed that all of the conclusions for KQ2 remained valid.

4. Conclusion

Summary results and conclusions according to the information collated from different sources (updating signals from studies identified through the update search, safety surveillance alerts, and expert opinion) are provided in Table 1 (Summary Table). Based on the assessments, this CER is categorized in **Low** priority group for updating.

Key Question # 1

Signals from studies identified through the update search: No new evidence. **No Signal**

Experts: Five of the experts stated that all of the conclusions for key question #1 are still valid. The sixth expert stated that one of the conclusions for key question #1 was invalid.

Safety surveillance alerts: None

Conclusion: **Up to date**

Key Questions # 2

Signals from studies identified through the update search: No new evidence. **No Signal**

Experts: Five experts stated that all of the conclusions for key question #2 are still valid. The sixth expert stated that one of the conclusions for key question #2 was invalid.

Safety surveillance alerts: None

Conclusion: **Up to date**

Key Question # 3

Signals from studies identified through the update search: No new evidence. **No Signal.**

Experts: All experts stated that the conclusions for key question #3 are still valid

Safety surveillance alerts: None

Conclusion: **Up to date**

Key Question # 4

Signals from studies identified through the update search: No qualitative or quantitative signal was identified. **No Signal.**

Experts: All experts stated that the conclusions for key question #4 are still valid

Safety surveillance alerts: None

Conclusion: **Up to date**

Key Question # 5

Signals from studies identified through the update search: No new evidence. **No Signal**

Experts: All experts stated that the conclusions for key question #5 are still valid

Safety surveillance alerts: None

Conclusion: **Up to date**

Table 1. Summary Table

Conclusions from CER's Executive Summary	Update literature search results	Signals for updating		FDA surveillance alerts	Expert opinion	Conclusion on validity of CER conclusion(s)
		Qualitative	Quantitative			
Key Question 1. In people with hypertension (adults and children), does self-measured blood pressure monitoring (SMBP), compared with usual care or other interventions without SMBP, have an effect on clinically important outcomes?						
a. How does SMBP monitoring compare with usual care or other interventions without SMBP in its effect on relevant clinical outcomes (cardiovascular events, mortality, patient satisfaction, quality of life, and adverse events related to antihypertensive agents)?						
b. How does SMBP monitoring compare with usual care or other interventions without SMBP in its effect on relevant surrogate outcomes (cardiac measures: LVH, LVM, LVMI) and intermediate outcomes (BP control, BP treatment adherence, or health care process measures)?						
SMBP Alone Versus Usual Care: Clinical Outcomes The strength of evidence is <i>insufficient</i> regarding a difference between SMBP versus usual care for clinical outcomes. No studies reported on clinical outcomes.	No new evidence	NA	NA	None	All six experts agreed that there is no evidence sufficient to invalidate the findings of CER thereby rendering this CER conclusion still valid.	Up to date
SMBP Alone Versus Usual Care: BP Outcomes The strength of evidence is <i>moderate</i> for a small improvement in BP control using SMBP alone compared with usual care, based on statistically significant findings at 6 months and a trend at 12 months. Of 24 studies that compared SMBP alone versus usual care, 22 were randomized controlled trials (RCTs) and 2 were quasi-RCTs. The studies were heterogeneous in terms of the brand and type of SMBP monitor, followup duration, and baseline BP control. Individual studies mostly found greater (although nonsignificant) rates of achieving BP control with SMBP monitoring alone than with usual care, but meta-analysis of the small number of available studies showed that SMBP	No new evidence	NA	NA	None	Five experts agreed that there is no evidence sufficient to invalidate the findings of the CER thereby rendering this conclusion still valid. The sixth expert suggested an addition study to confirm the findings of this conclusion ⁶ . This study had pooled results resulting in indistinguishable comparator groups and was thus excluded from this report.	Up to date

<p>alone was not associated with a significantly increased probability of achieving a predefined BP target at either 6 or 12 months. Sixteen studies reported continuous outcomes of net changes in clinic systolic BP (SBP) and diastolic BP (DBP). Meta-analyses revealed no significant effect at 2 months followup. Statistically significant differences favoring SMBP monitoring alone over usual care were, however, found at 6 months for SBP and DBP (SBP/DBP 3.1/2.0 mmHg), but not at 12 months (SBP/DBP 1.2/0.8 mmHg). Meta-analyses showed statistical heterogeneity at 6 and 12 months. The meta-analyses for 6- and 12-month BP outcome included five and six studies, respectively, with one quality A study in each meta-analysis. Only one RCT reported followup data beyond 12 months; significant reductions were found in SBP and DBP at 24 months with SMBP.</p> <p>Comparisons of SMBP alone with usual care for the outcomes of ambulatory BP measurements (24 hour, awake, and asleep) were based on a small number of studies that reported contradictory results. Meta-analysis of a small number of studies for the net changes in 24-hour ambulatory SBP and DBP at 2 months found no significant differences between SMBP alone and usual care. There were not enough studies to be subjected to meta-analysis for longer durations of followup. The studies of awake and asleep ambulatory BP fairly consistently favored SMPB alone over usual care, although most did not find a statistically significant difference.</p>						
<p>SMBP Alone Versus Usual Care: Surrogate and Intermediate Outcomes</p> <p>The strength of evidence is <i>low</i> and fails to support a difference between SMBP alone</p>	No new evidence	NA	NA	None	All six experts agreed that there is no evidence sufficient to invalidate the findings of CER thereby rendering this CER conclusion still valid.	Up to date

versus usual care for surrogate and intermediate outcomes. Other outcomes examined included quality of life (in three trials), medication number and dosage (in eight trials), medication adherence (in seven trials), left ventricular mass index (in one trial), and patient satisfaction with health care service (in one trial). The number of studies addressing each of these outcomes was low, and there was a lack of consistency in outcome definitions.						
SMBP Alone Versus Usual Care: Number of Health Care Encounters The strength of evidence is <i>low</i> and fails to support a difference between SMBP alone versus usual care for the number of health care encounters. Six studies reported on health care encounters. The majority of studies found no difference between SMBP alone and usual care in the number of health care encounters; however, there was some inconsistency, as one study found an increase and two found a decrease in office visits in the SMBP versus usual-care groups.	No new evidence	NA	NA	None	All six experts agreed that there is no evidence sufficient to invalidate the findings of CER thereby rendering this CER conclusion still valid.	Up to date
SMBP Plus Additional Support Versus Usual Care: Clinical Outcomes The strength of evidence is <i>insufficient</i> regarding a difference between SMBP plus additional support versus usual care for clinical outcomes. One quality C study reported on mortality and end-stage renal disease.	No new evidence	NA	NA	None	All six experts agreed that there is no evidence sufficient to invalidate the findings of CER thereby rendering this CER conclusion still valid.	Up to date
SMBP Plus Additional Support Versus Usual Care: BP Outcomes The strength of evidence is <i>high</i> and supports an improvement in BP control using SMBP with some form of additional support compared to usual care, based on consistent findings in	No new evidence	NA	NA	None	Four of the experts agreed that there is no evidence sufficient to invalidate the findings of CER thereby rendering this CER conclusion still valid. One expert suggested that the conclusion was still valid and offered another study to confirm the findings. ⁵ This study did not	Up to date

<p>quality A trials. Thirteen of 24 studies reported a statistically significant reduction in either SBP or DBP at followup favoring the SMBP with additional support intervention. All six quality A trials reported a significant mean net reduction in SBP (ranging from 3.4 to 8.9 mmHg) or DBP (ranging from 1.9 to 4.4 mmHg) in the intervention group compared with usual care at up to 12 months followup. The modalities of support added to SMBP in these six trials were telemonitoring and counseling on patient adherence to antihypertensive medications; Web-based pharmacist counseling; telemonitoring with self-titration of antihypertensive medications; telemonitoring with nurse videoconference; behavioral management; and medication management. The remaining seven studies reporting results favoring SMBP with additional support (in both SBP and DBP) used similarly diverse modes of support. Four studies provided results after 12 months. The single quality A trial found no difference between groups at 18 months followup; the other three trials each reported statistically significant mean net BP reductions for followup periods of 18 to 60 months.</p> <p>Across studies, it is not possible to state with certainty whether one form of additional support is superior, as the modalities of additional support examined varied in their primary intent, ancillary equipment and educational materials, followup personnel, and algorithms for medication adjustments. In addition, no form of additional support was examined by more than one trial.</p>					<p>answer this key question but was included in the results for key question 4.</p> <p>Another expert stated that this conclusion is invalid and nominated two references to support their statement.^{7,8} Both of these references were excluded – the first one did not have an appropriate comparison group,⁷ and the second one was a statement guide that did not provide data to answer any of the key questions in this report.⁸</p>	
<p>SMBP Plus Additional Support Versus Usual Care: Surrogate and Intermediate Outcomes</p> <p>The strength of evidence is <i>low</i> and fails to</p>	No new evidence	NA	NA	None	<p>All six experts agreed that there is no evidence sufficient to invalidate the findings of CER thereby rendering this CER conclusion still valid.</p>	Up to date

support a difference between SMBP plus additional support versus usual care for surrogate and intermediate outcomes. Additional support included counseling, education, and Web support. Outcomes examined included quality of life (in 3 trials), medication number and dosage (in 11 trials), medication adherence (in 6 trials), and adverse drug reactions (in 1 trial). The number of studies addressing each of these outcomes was low, and there was a lack of consistency in outcome definitions.						
SMBP Plus Additional Support Versus Usual Care: Number of Health Care Encounters The strength of evidence is <i>low</i> and fails to support a difference between SMBP plus additional support versus usual care for the number of health care encounters. Eight studies reported on health care encounters. Results were mixed, with five studies finding no difference between groups, one study finding fewer visits in the SMBP plus additional support group, one finding more visits in the SMBP plus additional support group, and one reporting mixed findings. The quality of included studies for this outcome was poor, and the results were inconclusive.	No new evidence	NA	NA	None	All six experts agreed that there is no evidence sufficient to invalidate the findings of CER thereby rendering this CER conclusion still valid.	Up to date
Key Question 2. In trials of SMBP monitoring, how do clinical, surrogate, and intermediate outcomes (including SMBP monitoring adherence) vary by the type of additional support provided?						
SMBP Plus Additional Support Versus SMBP Without Additional Support or With Less Intense Additional Support: Clinical Outcomes The strength of evidence is <i>insufficient</i> regarding a difference between SMBP plus additional support versus SMBP without additional support or with less intense additional support for clinical outcomes. No studies reported on clinical	No new evidence	NA	NA	None	Five experts agreed that there is no evidence sufficient to invalidate the findings of CER thereby rendering this CER conclusion still valid. The sixth expert stated that this conclusion is invalid and suggested a statement guide as additional support for this statement. ⁸ This reference was excluded as it does not provide data to answer this key question /	Up to date

outcomes.					conclusion.	
<p>SMBP Plus Additional Support Versus SMBP Without Additional Support or With Less Intense Additional Support: Blood Pressure Outcomes</p> <p>The strength of evidence is <i>low</i> and fails to support a difference in BP effects between SMBP plus additional support versus SMBP with no additional support or with less intense additional support. This rating is based on the findings of the majority of comparisons, which failed to show a difference for the additional support or the more intense support. In addition, the studies that indicated benefit included only one rated as quality A. Of the 12 studies, 11 were RCTs and 1 was a quasi-RCT. The studies were highly heterogeneous, primarily in the types of additional support used. Additional support consisted of a mixture of behavioral interventions or disease management by a nurse or pharmacist, medication management, educational interventions, electronic transmission of BP measurements, Web sites/training portals for patient provider communication, BP recording cards, BP and medication tracking tool, hypertension information leaflets, and home visits. Change in medication management as a result of the monitoring could be initiated by the patient, nurse, pharmacist, or primary care physician.</p> <p>Four trials found statistically significant benefits favoring more intense additional support for either SBP, DBP, BP control, or combinations thereof. Only one study was rated quality A. It showed consistent benefit for continuous SBP and DBP outcomes and for a categorical BP outcome. The additional support examined in this study was pharmacist counseling added to SMBP</p>	No new evidence	NA	NA	None	<p>Five experts agreed that there is no evidence sufficient to invalidate the findings of CER thereby rendering this CER conclusion still valid.</p> <p>The sixth expert stated that this conclusion is invalid and nominated an additional reference to support their statement.⁷ This reference was excluded as it did not have an appropriate comparison group.</p>	Up to date

plus use of personalized Web training. The other eight trials (seven full reports and one abstract) were indeterminate. Two studies provided results beyond 12 months. These were nonsignificant or of uncertain statistical significance. Across studies, no clear patterns could be discerned to explain the heterogeneity in results. The small number of studies and their distribution across different categories of additional support make it impossible to draw conclusions regarding the potential effects of any specific additional support or its interactions with SMBP.						
<p>SMBP Plus Additional Support Versus SMBP Without Additional Support or With Less Intense Additional Support: Surrogate and Intermediate Outcomes</p> <p>The strength of evidence is <i>low</i> and fails to support a difference between SMBP plus additional support versus SMBP without additional support or with less intense additional support for clinical, surrogate, and intermediate outcomes. Outcomes examined included quality of life (two trials), mental health (one trial), medication number and dosage (five trials), medication adherence (three trials), and adverse drug reactions (one trial). The number of studies addressing each of these outcomes was low, and there was a lack of consistency in outcome definitions.</p>	No new evidence	NA	NA	None	All six experts agreed that there is no evidence sufficient to invalidate the findings of CER thereby rendering this CER conclusion still valid.	Up to date

SMBP Plus Additional Support Versus SMBP Without Additional Support or With Less Intense Additional Support: Number of Health Care Encounters The strength of evidence is <i>low</i> and fails to support a difference for number of health care encounters between groups receiving SMBP plus additional support versus SMBP without additional support or with less intense additional support. Five trials reported number of health care encounters. Additional support included counseling by a nurse or pharmacist, behavioral intervention, medication management, and telemedicine. None of the studies found a difference in number of health care encounters through visits or hospitalizations. One study found that communication via email or telephone increased in those assigned to a pharmacist in addition to SMBP with Web training.	No new evidence	NA	NA	None	All six experts agreed that there is no evidence sufficient to invalidate the findings of CER thereby rendering this CER conclusion still valid.	Up to date
Key Question 3. How do different devices for SMBP monitoring compare with each other (specifically semiautomatic or automatic vs. manual) in their effects on clinical, surrogate, and intermediate outcomes (including SMBP monitoring adherence)?						
No trial addressed this Key Question.	No new evidence	NA	NA	None	All six experts agreed that there is no evidence sufficient to invalidate the findings of CER thereby rendering this CER conclusion still valid.	Up to date
Key Question 4. In trials of SMBP monitoring, how does achieving BP control relate to clinical and surrogate outcomes?						
No trials answered this question in the original CER.	1 RCT^s	No signal This study did not directly answer key question 4 however it informs choice of home BP.	No signal The study did not provide new evidence.	None	All six experts agreed that there is no evidence sufficient to invalidate the findings of CER thereby rendering this CER conclusion still valid.	Up to date

		TC BP: <125/<80 mm Hg UC BP: 125- 134/80-84 mm Hg				
Key Question 5. How does adherence with SMBP monitoring vary by patient factors?						
There is an <i>insufficient</i> level of evidence regarding predictors of SMBP adherence. One study investigated predictors for adherence to SMBP monitoring (with telephonic transmission of BP measurements, hypertension education, and telephone counseling by a nurse) and its relationship to BP control in 377 middle-aged Korean Americans. Older age was independently associated with greater adherence to SMBP monitoring, and the presence of depression was independently associated with lower adherence.	No new evidence	NA	NA	None	All six experts agreed that there is no evidence sufficient to invalidate the findings of CER thereby rendering this CER conclusion still valid	Up to date
CER=comparative effectiveness review; SMBP=Self-measured blood pressure monitoring BP = blood pressure SBP=Systolic blood pressure; DBP=diastolic blood pressure						

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Appendix A: Search Methodology

All MEDLINE, CENTRAL, and Embase searches were limited to the following journals:

General biomedical – Annals of Internal Medicine, BMJ, JAMA, Lancet, and New England Journal of Medicine

Specialty journals – American Journal of Hypertension, Hypertension, Journal of Human Hypertension, Journal of Hypertension, Circulation

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Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) <1946 to Present>, EBM Reviews - Cochrane Central Register of Controlled Trials <July 2012> Search Strategy:

- 1 exp Blood Pressure Monitoring, Ambulatory/ (6924)
- 2 exp Blood Pressure Monitors/ (2007)
- 3 exp Blood Pressure/ (256820)
- 4 exp hypertension/ (209950)
- 5 exp Self Care/ (38616)
- 6 (3 or 4) and 5 (1163)
- 7 ((blood pressure or hypertens\$) and self and (measure\$ or monitor\$ or care or manage\$)).mp. (7686)
- 8 1 or 2 or 6 or 7 (15784)
- 9 randomized controlled trial.pt. (644799)
- 10 controlled clinical trial.pt. (166547)
- 11 randomized controlled trials/ (87525)
- 12 Random Allocation/ (95712)
- 13 Double-blind Method/ (212300)
- 14 Single-Blind Method/ (26902)
- 15 clinical trial.pt. (748743)
- 16 Clinical Trials.mp. or exp Clinical Trials/ (313956)
- 17 (clinic\$ adj25 trial\$).tw. (284269)
- 18 ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj (mask\$ or blind\$)).tw. (242996)
- 19 Placebos/ (51696)
- 20 placebo\$.tw. (259862)
- 21 random\$.tw. (914590)
- 22 trial\$.tw. (718708)
- 23 (latin adj square).tw. (3928)
- 24 Comparative Study.tw. or Comparative Study.pt. (1749789)
- 25 exp Evaluation studies/ (169853)
- 26 Follow-Up Studies/ (487538)
- 27 Prospective Studies/ (383053)
- 28 (control\$ or prospectiv\$ or volunteer\$).tw. (2973448)
- 29 Cross-Over Studies/ (52901)
- 30 or/9-29 (5560205)
- 31 exp cohort studies/ or exp prospective studies/ or exp retrospective studies/ or exp epidemiologic studies/ or exp case-control studies/ (1541016)

32 (cohort or retrospective or prospective or longitudinal or observational or follow-up or followup or
 registry).af. (1899650)
 33 case-control.af. or (case adj10 control).tw. (186707)
 34 ep.fs. (1085441)
 35 31 or 32 or 33 or 34 (2823338)
 36 8 and (30 or 35) (12090)
 37 limit 36 to humans [Limit not valid in CCTR; records were retained] (11780)
 38 (home adj20 blood pressure).mp. (2277)
 39 (exp telemedicine/ or exp self-examination/) and (exp Blood pressure/ or exp Hypertension/) (227)
 40 or/9-37 (6748032)
 41 40 and (38 or 39) (1853)
 42 37 or 41 (12622)
 43 ("20110120" or "20110121" or "20110124" or "20110125" or "20110126" or "20110127" or
 "20110128" or "20110131" or 201102* or 201103* or 201104* or 201105* or 201106* or 201107* or
 201108* or 201109* or 201110* or 201111* or 201112* or 2012*).ed. (1504749)
 44 lancet.jn. (129082)
 45 jama.jn. (62878)
 46 "annals of internal medicine".jn. (28724)
 47 bmj.jn. (74310)
 48 "new england journal of medicine".jn. (66151)
 49 "american journal of hypertension".jn. (6685)
 50 hypertension.jn. (12531)
 51 "journal of human hypertension".jn. (4318)
 52 "journal of hypertension".jn. (8331)
 53 circulation.jn. (40313)
 54 or/44-53 (433323)
 55 42 and 43 and 54 (136)
 56 55 use prmz (136)
 57 exp Blood Pressure Monitoring, Ambulatory/ (6924)
 58 exp Blood Pressure Monitors/ (2007)
 59 exp Blood Pressure/ (256820)
 60 exp hypertension/ (209950)
 61 exp Self Care/ (38616)
 62 (59 or 60) and 61 (1163)
 63 ((blood pressure or hypertens\$) and self and (measure\$ or monitor\$ or care or manage\$)).mp.
 (7686)
 64 57 or 58 or 62 or 63 (15784)
 65 randomized controlled trial.pt. (644799)
 66 controlled clinical trial.pt. (166547)
 67 randomized controlled trials/ (87525)
 68 Random Allocation/ (95712)
 69 Double-blind Method/ (212300)
 70 Single-Blind Method/ (26902)
 71 clinical trial.pt. (748743)
 72 Clinical Trials.mp. or exp Clinical Trials/ (313956)
 73 (clinic\$ adj25 trial\$).tw. (284269)
 74 ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj (mask\$ or blind\$)).tw. (242996)
 75 Placebos/ (51696)
 76 placebo\$.tw. (259862)
 77 random\$.tw. (914590)
 78 trial\$.tw. (718708)

79 (randomized control trial or clinical control trial).sd. (235129)
 80 (latin adj square).tw. (3928)
 81 Comparative Study.tw. or Comparative Study.pt. (1749789)
 82 exp Evaluation studies/ (169853)
 83 Follow-Up Studies/ (487538)
 84 Prospective Studies/ (383053)
 85 (control\$ or prospectiv\$ or volunteer\$).tw. (2973448)
 86 Cross-Over Studies/ (52901)
 87 or/65-86 (5674610)
 88 exp cohort studies/ or exp prospective studies/ or exp retrospective studies/ or exp epidemiologic
 studies/ or exp case-control studies/ (1541016)
 89 (cohort or retrospective or prospective or longitudinal or observational or follow-up or followup or
 registry).af. (1899650)
 90 case-control.af. or (case adj10 control).tw. (186707)
 91 ep.fs. (1085441)
 92 88 or 89 or 90 or 91 (2823338)
 93 64 and (87 or 92) (12104)
 94 (home adj20 blood pressure).mp. (2277)
 95 (exp telemedicine/ or exp self-examination/) and (exp Blood pressure/ or exp Hypertension/) (227)
 96 or/65-93 (6860075)
 97 96 and (94 or 95) (1863)
 98 93 or 97 (12938)
 99 (2011* or 2012*).up. (22204769)
 100 lancet.jn. (129082)
 101 jama.jn. (62878)
 102 "annals of internal medicine".jn. (28724)
 103 bmj.jn. (74310)
 104 "new england journal of medicine".jn. (66151)
 105 "american journal of hypertension".jn. (6685)
 106 hypertension.jn. (12531)
 107 "journal of human hypertension".jn. (4318)
 108 "journal of hypertension".jn. (8331)
 109 circulation.jn. (40313)
 110 or/100-109 (433323)
 111 98 and 99 and 110 (2265)
 112 111 use cctr (432)
 113 56 or 112 (568)
 114 remove duplicates from 113 (535)
 115 114 use prmz (119)
 116 114 use cctr (416)

Appendix B: Updating Signals

Qualitative signals*

Potentially invalidating change in evidence

This category of signals (A1-A3) specifies findings from a pivotal trial**, meta-analysis (with at least one new trial), practice guideline (from major specialty organization or published in peer-reviewed journal), or recent textbook (e.g., *Up-To-Date*):

- Opposing findings (e.g., effective vs. ineffective) – **A1**
- Substantial harm (e.g., the risk of harm outweighs the benefits) – **A2**
- A superior new treatment (e.g., new treatment that is significantly superior to the one assessed in the original CER) – **A3**

Major change in evidence

This category of signals (A4-A7) refers to situations in which there is a clear potential for the new evidence to affect the clinical decision making. These signals, except for one (A7), specify findings from a pivotal trial, meta-analysis (with at least one new trial), practice guideline (from major specialty organization or published in peer-reviewed journal), or recent textbook (e.g., *Up-To-Date*):

- Important changes in effectiveness short of “opposing findings” – **A4**
- Clinically important expansion of treatment (e.g., to new subgroups of subjects) – **A5**
- Clinically important caveat – **A6**
- Opposing findings from meta-analysis (in relation to a meta-analysis in the original CER) or non-pivotal trial – **A7**

* Please, see Shojania et al. 2007⁹ for further definitions and details

**A pivotal trial is defined as: 1) a trial published in top 5 general medical journals such as: Lancet, JAMA, Annals of Intern Med, BMJ, and NEJM. Or 2) a trial not published in the above top 5 journals but have a sample size of at least triple the size of the previous largest trial in the original CER.

Appendix B: Updating Signals (Continued)

Quantitative signals (B1-B2)*

Change in statistical significance (B1)

Refers to a situation in which a statistically significant result in the original CER is now NOT statistically significant or vice versa- that is a previously non-significant result become statistically significant. For the ‘borderline’ changes in statistical significance, at least one of the reports (the original CER or new updated meta-analysis) must have a p-value outside the range of border line (0.04 to 0.06) to be considered as a quantitative signal for updating.

Change in effect size of at least 50% (B2)

Refers to a situation in which the new result indicates a relative change in effect size of at least 50%. For example, if relative risk reduction (RRR) new / RRR old ≤ 0.5 or RRR new / RRR old ≥ 1.5 . Thus, if the original review has found RR=0.70 for mortality, this implies RRR of 0.3. If the updated meta-analytic result for mortality were 0.90, then the updated RRR would be 0.10, which is less than 50% of the previous RRR. In other words the reduction in the risk of death has moved from 30% to 10%. The same criterion applied for odds ratios (e.g., if previous OR=0.70 and updated result were OR=0.90, then the new reduction in odds of death (0.10) would be less 50% of the magnitude of the previous reduction in odds (0.30). For risk differences and weighted mean differences, we applied the criterion directly to the previous and updated results (e.g., RD new / RD old ≤ 0.5 or RD new / RD old ≥ 1.5).

* Please, see Shojania et al. 2007⁹ for further definitions and details

Appendix C: Evidence Table

Author year Study name (if applicable)	Study design	Subjects	Treatment groups (n; dose)	Treatment duration	Outcomes and findings
Key Question 1. In people with hypertension (adults and children), does self-measured blood pressure monitoring (SMBP), compared with usual care or other interventions without SMBP, have an effect on clinically important outcomes?					
a. How does SMBP monitoring compare with usual care or other interventions without SMBP in its effect on relevant clinical outcomes (cardiovascular events, mortality, patient satisfaction, quality of life, and adverse events related to antihypertensive agents)?					
b. How does SMBP monitoring compare with usual care or other interventions without SMBP in its effect on relevant surrogate outcomes (cardiac measures: LVH, LVM, LVMI) and intermediate outcomes (BP control, BP treatment adherence, or health care process measures)?					
No new relevant evidence was identified	NA	NA	NA	NA	NA
Key Question 2. In trials of SMBP monitoring, how do clinical, surrogate, and intermediate outcomes (including SMBP monitoring adherence) vary by the type of additional support provided?					
No new relevant evidence was identified	NA	NA	NA	NA	NA
Key Question 3. How do different devices for SMBP monitoring compare with each other (specifically semiautomatic or automatic vs. manual) in their effects on clinical, surrogate, and intermediate outcomes (including SMBP monitoring adherence)?					
No new relevant evidence was identified	NA	NA	NA	NA	NA
Key Question 4. In trials of SMBP monitoring, how does achieving BP control relate to clinical and surrogate outcomes?					
Asayama 2012 ⁵	RCT	3518 patients with untreated systolic/diastolic home blood pressure of 135-179/85-119 mm Hg. mean age: 59.6 yrs; male%: 50	Tight control blood pressure: <125/<80 mm Hg + ACE's, ARB's or CCB's n= 1759 Usual control blood pressure: 125-134/80-84 mm Hg + ACE's, ARB's or CCB's n=1759	Median follow-up: 5.3 years	Tight control vs. Usual control <u>Clinical outcomes:</u> Cardiovascular death plus stroke and myocardial infarction: 26 vs. 25 patients (hazard ratio, 1.02; 95% CI 0.59-1.77; P=0.94) <u>Intermediate outcomes:</u> HBP reduction: 21.3/13.1 mm Hg vs. 22.7/13.9 mm Hg, P=0.018/0.020 Use of antihypertensive drugs: 1.82 vs. 1.74 defined daily doses, P=0.045) HBP Targets: 37.4% vs. 63.5%, P<0.0001 If treated Systolic BP \geq 131.6 mm Hg, then 5 year risk for CV death

Author year Study name (if applicable)	Study design	Subjects	Treatment groups (n; dose)	Treatment duration	Outcomes and findings
					plus stroke and MI was minimal ($\leq 1\%$). This study shows that adjusting antihypertensive drug treatment based on HBP is feasible and suggests that a systolic HBP target of 130 mm Hg is achievable and safe.
Key Question 5. How does adherence with SMBP monitoring vary by patient factors?					
No new relevant evidence was identified	NA	NA	NA	NA	NA
SMBP: Self-measured blood pressure monitoring; ACE: angiotensin converting enzyme inhibitors; ARB: angiotensin receptor blockers; CCB: calcium channel blockers vs.: versus; HBP: Home blood pressure; BP: Blood pressure; CV: Cardiovascular; MI: Myocardial infarction					

Appendix D: Questionnaire Matrix

Self-Measured Blood Pressure Monitoring: Comparative Effectiveness

AHRQ Publication No. 12-EHC002-EF, January 2012

Access to full report: <http://effectivehealthcare.ahrq.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=893>

Clinical expert name:

Conclusions from CER (executive summary)	Is the conclusion(s) in this CER still valid? (Yes/No/Don't know)	Are you aware of any new evidence that is sufficient to invalidate the finding(s) in CER? (Yes/No/Don't know) If yes, please provide references	Comments
<p>Key Question 1. In people with hypertension (adults and children), does self-measured blood pressure monitoring (SMBP), compared with usual care or other interventions without SMBP, have an effect on clinically important outcomes?</p> <p>a. How does SMBP monitoring compare with usual care or other interventions without SMBP in its effect on relevant clinical outcomes (cardiovascular events, mortality, patient satisfaction, quality of life, and adverse events related to antihypertensive agents)?</p> <p>b. How does SMBP monitoring compare with usual care or other interventions without SMBP in its effect on relevant surrogate outcomes (cardiac measures: LVH, LVM, LVMI) and intermediate outcomes (BP control, BP treatment adherence, or health care process measures)?</p>			
<p>SMBP Alone Versus Usual Care: Clinical Outcomes</p> <p>The strength of evidence is <i>insufficient</i> regarding a difference between SMBP versus usual care for clinical outcomes. No studies reported on clinical outcomes.</p>			
<p>SMBP Alone Versus Usual Care: BP Outcomes</p> <p>The strength of evidence is <i>moderate</i> for a small improvement in BP control using SMBP alone compared with usual care, based on statistically significant findings at 6 months and a trend at 12 months. Of 24 studies that compared SMBP alone versus usual care, 22 were randomized controlled trials (RCTs) and 2 were quasi-RCTs. The studies were heterogeneous in terms of the brand and type of SMBP monitor, followup</p>			

<p>duration, and baseline BP control.</p> <p>Individual studies mostly found greater (although nonsignificant) rates of achieving BP control with SMBP monitoring alone than with usual care, but meta-analysis of the small number of available studies showed that SMBP alone was not associated with a significantly increased probability of achieving a predefined BP target at either 6 or 12 months. Sixteen studies reported continuous outcomes of net changes in clinic systolic BP (SBP) and diastolic BP (DBP). Meta-analyses revealed no significant effect at 2 months followup. Statistically significant differences favoring SMBP monitoring alone over usual care were, however, found at 6 months for SBP and DBP (SBP/DBP 3.1/2.0 mmHg), but not at 12 months (SBP/DBP 1.2/0.8 mmHg). Meta-analyses showed statistical heterogeneity at 6 and 12 months. The meta-analyses for 6- and 12-month BP outcome included five and six studies, respectively, with one quality A study in each meta-analysis. Only one RCT reported followup data beyond 12 months; significant reductions were found in SBP and DBP at 24 months with SMBP.</p> <p>Comparisons of SMBP alone with usual care for the outcomes of ambulatory BP measurements (24 hour, awake, and asleep) were based on a small number of studies that reported contradictory results. Meta-analysis of a small number of studies for the net changes in 24-hour ambulatory SBP and DBP at 2 months found no significant differences between SMBP alone and usual care. There were not enough studies to be subjected to meta-analysis for longer durations of followup. The studies of awake and asleep ambulatory BP fairly consistently favored SMPB alone over usual care, although most did not find a statistically significant difference.</p>			
<p>SMBP Alone Versus Usual Care: Surrogate and Intermediate Outcomes</p> <p>The strength of evidence is <i>low</i> and fails to support a difference between SMBP alone versus usual care for surrogate and intermediate outcomes. Other outcomes examined included quality of life (in three trials), medication number and dosage (in eight trials), medication adherence (in seven trials), left ventricular mass index (in one trial), and patient satisfaction with health care service (in one trial). The number of studies addressing each of these outcomes was low, and there was a lack of consistency in outcome definitions.</p>			
<p>SMBP Alone Versus Usual Care: Number of Health Care Encounters</p> <p>The strength of evidence is <i>low</i> and fails to support a difference between SMBP alone versus usual care for the number of health care encounters. Six studies reported on health care encounters. The majority of studies found no difference between SMBP alone and usual care in the number of health care encounters; however, there was some inconsistency, as one study found an increase and two found a decrease in office visits</p>			

in the SMBP versus usual-care groups.			
SMBP Plus Additional Support Versus Usual Care: Clinical Outcomes <p>The strength of evidence is <i>insufficient</i> regarding a difference between SMBP plus additional support versus usual care for clinical outcomes. One quality C study reported on mortality and end-stage renal disease.</p>			
SMBP Plus Additional Support Versus Usual Care: BP Outcomes <p>The strength of evidence is <i>high</i> and supports an improvement in BP control using SMBP with some form of additional support compared to usual care, based on consistent findings in quality A trials. Thirteen of 24 studies reported a statistically significant reduction in either SBP or DBP at followup favoring the SMBP with additional support intervention. All six quality A trials reported a significant mean net reduction in SBP (ranging from 3.4 to 8.9 mmHg) or DBP (ranging from 1.9 to 4.4 mmHg) in the intervention group compared with usual care at up to 12 months followup. The modalities of support added to SMBP in these six trials were telemonitoring and counseling on patient adherence to antihypertensive medications; Web-based pharmacist counseling; telemonitoring with self-titration of antihypertensive medications; telemonitoring with nurse videoconference; behavioral management; and medication management. The remaining seven studies reporting results favoring SMBP with additional support (in both SBP and DBP) used similarly diverse modes of support. Four studies provided results after 12 months. The single quality A trial found no difference between groups at 18 months followup; the other three trials each reported statistically significant mean net BP reductions for followup periods of 18 to 60 months.</p> <p>Across studies, it is not possible to state with certainty whether one form of additional support is superior, as the modalities of additional support examined varied in their primary intent, ancillary equipment and educational materials, followup personnel, and algorithms for medication adjustments. In addition, no form of additional support was examined by more than one trial.</p>			
SMBP Plus Additional Support Versus Usual Care: Surrogate and Intermediate Outcomes <p>The strength of evidence is <i>low</i> and fails to support a difference between SMBP plus additional support versus usual care for surrogate and intermediate outcomes. Additional support included counseling, education, and Web support. Outcomes examined included quality of life (in 3 trials), medication number and dosage (in 11 trials), medication adherence (in 6 trials), and adverse drug reactions (in 1 trial). The</p>			

number of studies addressing each of these outcomes was low, and there was a lack of consistency in outcome definitions.			
<p>SMBP Plus Additional Support Versus Usual Care: Number of Health Care Encounters</p> <p>The strength of evidence is <i>low</i> and fails to support a difference between SMBP plus additional support versus usual care for the number of health care encounters. Eight studies reported on health care encounters. Results were mixed, with five studies finding no difference between groups, one study finding fewer visits in the SMBP plus additional support group, one finding more visits in the SMBP plus additional support group, and one reporting mixed findings. The quality of included studies for this outcome was poor, and the results were inconclusive.</p>			
<p>Key Question 2. In trials of SMBP monitoring, how do clinical, surrogate, and intermediate outcomes (including SMBP monitoring adherence) vary by the type of additional support provided?</p>			
<p>SMBP Plus Additional Support Versus SMBP Without Additional Support or With Less Intense Additional Support: Clinical Outcomes</p> <p>The strength of evidence is <i>insufficient</i> regarding a difference between SMBP plus additional support versus SMBP without additional support or with less intense additional support for clinical outcomes. No studies reported on clinical outcomes.</p>			
<p>SMBP Plus Additional Support Versus SMBP Without Additional Support or With Less Intense Additional Support: Blood Pressure Outcomes</p> <p>The strength of evidence is <i>low</i> and fails to support a difference in BP effects between SMBP plus additional support versus SMBP with no additional support or with less intense additional support. This rating is based on the findings of the majority of comparisons, which failed to show a difference for the additional support or the more intense support. In addition, the studies that indicated benefit included only one rated as quality A. Of the 12 studies, 11 were RCTs and 1 was a quasi-RCT. The studies were highly heterogeneous, primarily in the types of additional support used. Additional support consisted of a mixture of behavioral interventions or disease management by a nurse or pharmacist, medication management, educational interventions, electronic transmission of BP measurements, Web sites/training portals for patient provider communication, BP recording cards, BP and medication tracking tool, hypertension information leaflets, and home visits. Change in medication management as a result of the monitoring could be initiated by the patient, nurse, pharmacist, or primary care physician.</p>			

Four trials found statistically significant benefits favoring more intense additional support for either SBP, DBP, BP control, or combinations thereof. Only one study was rated quality A. It showed consistent benefit for continuous SBP and DBP outcomes and for a categorical BP outcome. The additional support examined in this study was pharmacist counseling added to SMBP plus use of personalized Web training. The other eight trials (seven full reports and one abstract) were indeterminate. Two studies provided results beyond 12 months. These were nonsignificant or of uncertain statistical significance. Across studies, no clear patterns could be discerned to explain the heterogeneity in results. The small number of studies and their distribution across different categories of additional support make it impossible to draw conclusions regarding the potential effects of any specific additional support or its interactions with SMBP.			
SMBP Plus Additional Support Versus SMBP Without Additional Support or With Less Intense Additional Support: Surrogate and Intermediate Outcomes The strength of evidence is <i>low</i> and fails to support a difference between SMBP plus additional support versus SMBP without additional support or with less intense additional support for clinical, surrogate, and intermediate outcomes. Outcomes examined included quality of life (two trials), mental health (one trial), medication number and dosage (five trials), medication adherence (three trials), and adverse drug reactions (one trial). The number of studies addressing each of these outcomes was low, and there was a lack of consistency in outcome definitions.			
SMBP Plus Additional Support Versus SMBP Without Additional Support or With Less Intense Additional Support: Number of Health Care Encounters The strength of evidence is <i>low</i> and fails to support a difference for number of health care encounters between groups receiving SMBP plus additional support versus SMBP without additional support or with less intense additional support. Five trials reported number of health care encounters. Additional support included counseling by a nurse or pharmacist, behavioral intervention, medication management, and telemedicine. None of the studies found a difference in number of health care encounters through visits or hospitalizations. One study found that communication via email or telephone increased in those assigned to a pharmacist in addition to SMBP with Web training.			
Key Question 3. How do different devices for SMBP monitoring compare with each other (specifically semiautomatic or automatic vs. manual) in their effects on clinical, surrogate, and intermediate outcomes (including SMBP monitoring adherence)?			
No trial addressed this Key Question			

Key Question 4. In trials of SMBP monitoring, how does achieving BP control relate to clinical and surrogate outcomes?			
No trial addressed this Key Question			
Key Question 5. How does adherence with SMBP monitoring vary by patient factors?			
There is an <i>insufficient</i> level of evidence regarding predictors of SMBP adherence. One study investigated predictors for adherence to SMBP monitoring (with telephonic transmission of BP measurements, hypertension education, and telephone counseling by a nurse) and its relationship to BP control in 377 middle-aged Korean Americans. Older age was independently associated with greater adherence to SMBP monitoring, and the presence of depression was independently associated with lower adherence			
CER=comparative effectiveness review; SMBP=Self-measured blood pressure monitoring BP = blood pressure SBP=Systolic blood pressure; DBP=diastolic blood pressure			